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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,456	10/19/2002	Toshio Kawai	020.0001	4033
29453 7590 02/21/2007 JUDGE & MURAKAMI IP ASSOCIATES DOJIMIA BUILDING, 7TH FLOOR 6-8 NISHITEMMA 2-CHOME, KITA-KU OSAKA-SHI, 530-0047 JAPAN			EXAMINER BABIC, CHRISTOPHER M	
			ART UNIT	PAPER NUMBER
			1637	
			MAIL DATE	DELIVERY MODE
			02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/065,456

Applicant(s)

KAWAI, TOSHIO

Examiner

Christopher M. Babic

Art Unit

1637

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 4-13.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 4-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Haff et al. (EP 0 636 413 A2).

Applicant's arguments with respect to the above reference have been fully considered but they are not persuasive.

Initially, it is noted that the claim amendments presented in the above reply DO NOT overcome the outstanding rejections over Haff.

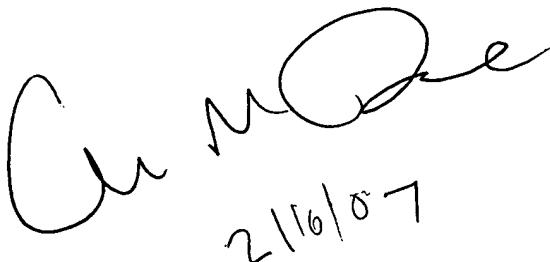
With regard to the term --endless--, as submitted before in the previous Office Action dated August 28, 2006, the teachings of Haff suggest continuously flowing the same reaction mixture through multiple amplification cycles via an --endless-- recirculation path. Figure 2 clearly suggests feeding an amplification reaction mixture unidirectionally through the appropriate temperature regions. Thus, it would have been prima facie obvious to apply a unidirectional flow to the apparatus of Figure 1, which, in order to effectively amplify the nucleic acid, would necessitate the "recycling" of the reaction mixture through the apparatus. Furthermore, it is noted that Figures 1 and 2 show a TWO TEMPERATURE amplification process which lends itself to apparatus configurations that would reciprocate the reaction mixture rather than recycling it. In a THREE TEMPERATURE amplification process, which is clearly envisioned by Haff (col. 9, lines 30-35, for example), one of ordinary skill in the art at the time of invention would have known that the reaction mixture is to be moved successively through temperatures causing DENATURING, ANNEALING, EXTENSION, then back to DENATURING to start another cycle of amplification. One of ordinary skill in the art at the time of invention would have recognized that it is counter-productive and contrary to well known scientific methodology to flow a reaction mixture from the EXTENSION temperature back to the ANNEALING temperature. Thus, the creation of an --endless-- recirculation path flows naturally from the teachings of Haff.

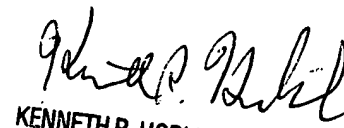
With regard to the term --circuit-feed--, absent any formal definition within the specification, terms are given their broadest reasonable interpretation. Haff clearly discloses that a CPU may be used to control reagent addition, temperature, cycle time, etc.. (col. 12, lines 20-50), which is interpreted to be a form of --circuit-feeding--.

Applicant further argues that Haff does not suggest coiling the reaction-mixture-containing capillary tube to control residence time and to increase the amount of reaction mixture exposed to a given temperature bath at one time. This argument is not persuasive because, as submitted before in the previous Office Action dated August 28, 2006, Haff et al. expressly teaches that "looping" the reaction tube can control the period of time a reaction mixture is at a certain temperature or series of temperatures. Furthermore, they disclose that the length of tubing is directly related to the residence time of the reaction mixture in each temperature zone, expressly highlighting that tubing of greater length is preferred to achieve better temperature control (col. 10, for example).

Applicant further argues that the present invention overcomes the art-recognized problem of scaling-up traditional PCR reaction volumes, pointing to Haff's discussion of this issue. This argument is not persuasive because, first, Haff teaches that the Figure 1 embodiment can perform PCR on a reaction volume of ANY scale (col. 9, lines 15-30, for example). Furthermore, even if the Haff disclosure did not envision reaction volumes of ANY scale, the present claims would still not be distinguished from Haff because there are no specific volume requirements within the claim. As submitted before in the previous Office Action dated August 28, 2006, the use of the term --tank-- does not patentably distinguish the present invention from the disclosure of Haff et al. even though the present invention appears to be a large-scale amplification apparatus. The term --tank-- is not defined in any manner within the specification or claim language itself that would require reaction volumes thought to be of a large-scale nature.

Thus, the rejections are maintained.


2/16/07


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER
2/20/07